10-20-05 09/640526 C08C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 003707.00009

In re U.S. Patent Number: 6,951,894 B1		)	Examiner: Edward J. Cain
Inventor:	Paul Clement Nicolson, et al.	)	Group Art Unit: 1714
Issued:	October 4, 2005	)	Confirmation No. 6172
For:	EXTENDED WEAR OPHTHALMIC LENS	)	

REQUEST FOR EXPEDITED CERTIFICATE OF CORRECTION

Attention of Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 35 U.S.C. § 254 and 37 C.F.R. 1.322, the Assignee of the above-identified patent, CIBA Vision Corporation ("Patentee"), requests an Expedited Certificate of Correction to correct mistakes in the above-identified patent. Attached is Form PTO/SB/44, in duplicate, indicating the requested corrections.

The corrections required due to Office error include the addition of sixteen (16) allowed claims that are not reflected in the issued patent and amendments to the claims that were previously filed but also not reflected in the issued patent. These corrections are:

In column 70, line 55, please change "polymerizing - said" to --polymerizing said--.

In column 71, line 21, please change "material and upper" to --material having upper--.

In column 72, line 4, please change "of grater than" to --of greater than--.

In column 72, line 4, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 72, line 6, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 72, line 65, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 73, line 1, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 73, line 62, please change "treatment is a" to --treatment includes a--.

In column 73, lines 63-65, please change "wherein said oxyperm polymerizable material is a fluorine macromer and said ionoperm polymerizable material" to --wherein said ionoperm polymerizable material--.

In column 74, line 16, please change "material comprises a fluorine macromer, and" to --material is formed from--.

In column 74, line 43, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 74, line 45, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 75, line 35, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 75, line 37, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 76, lines 3 and 4, please change "(b) polymerizing the core in an atmosphere substantially free from oxygen" to --(b) polymerizing the core formulation in an atmosphere substantially free from oxygen to form a biocompatible lens having a core and surfaces;--.

In column 76, line 8, please change "autoclaving lens" to --autoclaving said lens--.

In column 76, line 25, please change "wherein said ophthalmic lens" to --wherein said biocompatible lens--.

In column 77, lines 9 and 10, please change "54 including (c) said said lens being autoclaved at predetermined temperatures." to --54, said lens being sterilized.--

In column 77, line 39, please change "worn as extended wear lens that is worn for" to --worn as an extended wear lens for --.

In column 78, line 9, please change "worn as extended wear lens that is worn for" to --worn as an extended wear lens for--.

In column 79, line 12, please change "6.4x10-6 " to --$6.4x10^{-6}$--.

In column 79, line 14, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 80, line 22, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 80, line 24, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 80, after line 49, please add the following claims:

85. An extended wear contact lens comprising a core polymeric material and inner and outer surfaces that are more hydrophilic than said core polymeric material, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said extended wear contact lens can be continuously worn for at least fourteen days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

86. A siloxane hydrogel contact lens comprising a core polymeric material having hydrophilically modified surfaces that are more hydrophilic that said core material, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about $6.4x10^{-6}$ mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about $0.4x10^{-6}$ cm^2/min to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said hydrogel contact lens is adapted for at least 14 days of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

87. A biocompatible contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about $0.4x10^{-6}$ cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface treated to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote

adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous contact for 14 days.

88. A biocompatible sterilizable contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about $0.4x10^{-6}$ cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous contact for 30 days.

89. A contact lens comprising a polymeric material formed from at least:

(a) an ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide; and

(b) an oxyperm polymerizable material;

wherein said lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton ion permeability coefficient of greater than about $0.25x10^{-3}$ cm^2/sec, or (2) an Ionoflux diffusion coefficient of greater than about $1.3x10^{-5}$ mm^2/min, wherein said ion permeability is measured with respect to sodium ions;

wherein said lens is suitable for continuous, intimate contact with ocular tissue and ocular fluids while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours.

90. The contact lens of claim 89 wherein said ionoperm polymerizable material comprises both 2-hydroxyethyl methacrylate and N,N-dimethylacrylamide.

91. The contact lens of claim 90 wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer.

92. The contact lens of claim 91 wherein said polymeric material is further

formed from ethylene glycol dimethacrylate.

93. The contact lens of claim 92 wherein said lens is autoclaved without lowering either said oxygen transmissibility or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

94. The contact lens of claim 92 wherein said period of wear is at least 4 days.

95. The contact lens of claim 92 wherein said period of wear is at least 7 days.

96. The contact lens of claim 89 further comprising polyvinylpyrrolidone at a surface of said lens.

97. The contact lens of claim 96 wherein said polyvinylpyrrolidone coats said surface of said lens.

98. The contact lens of claim 89 wherein said period of wear is at least 4 days.

99. The contact lens of claim 89 wherein said period of wear is at least 7 days.

100. The contact lens of claim 89 wherein said lens has an equilibrium water content of about 10 to about 30 weight percent.

These mistakes occurred through the fault of the Patent and Trademark Office, as clearly disclosed by the records of the Office. Attached is a copy of the September 22, 2004 amendment as filed via facsimile, including the confirmation information showing receipt by the United States Patent and Trademark Office on September 22, 2004. Also attached are copies of amendments filed on February 11, 2002, February 26, 2002, and March 10, 2003. In view of the foregoing, the Patentee respectfully requests that an Expedited Certificate of Correction be issued for this patent and sent to the undersigned attorney.

The Patentee also requests correction of mistakes of clerical or typographical nature, or of minor character, which occurred in good faith. These mistakes were not the fault of the Patent and Trademark Office.

In column 77, line 61, please change "continous" to --continuous--.

In column 79, line 47, please change "continous" to --continuous--.

In column 80, line 18, please change "absorption" to --adsorption--.

In column 80, line 28, please change "continous" to --continuous--.

In column 80, line 49, please change "less that about" to --less than about--.

In the omitted claims, claims 85-100, Patentee requests the following corrections (with reference to the line numbers of the claims as set forth in the attached Form PTO/SB/44). The claims as listed *supra* and as set forth on the attached Form PTO/SB/44 include these corrections:

In claim 85, line 1, please change "inner and lower surfaces" to --inner and outer surfaces--.

In claim 89, line 7, please change "$1.3x10^{-3}$ mm^2/min" to --$1.3x10^{-5}$ mm^2/min--.

The correction to claim 85 is intended to make the claim language consistent, as reflected in the other claims of the patent (see, e.g., claim 88). The correction to claim 89 (previously claim 247) is consistent with the remarks made in support of the claim at the time the claim was added (see, e.g., p. 28, September 22, 2004 Amendment).

As the required corrections primarily are due to a United States Patent and Trademark Office error, Patentee does not believe that there is a fee due for this requested correction. However should there be a fee associated with the filing of these documents, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment of fees, to Deposit Account No. 19-0733. Should any questions arise with respect to this case that may be addressed by telephone, please feel free to contact the undersigned attorney.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Date: October 19, 2005

By: Rebecca P. Rokos

Rebecca P. Rokos
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. 6,951,894

APPLICATION NO. 09/640,526

ISSUE DATE: OCTOBER 4, 2005

INVENTORS: NICOLSON, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 70, line 55, please change "polymerizing - said" to --polymerizing said--.

In column 71, line 21, please change "material and upper" to --material having upper--.

In column 72, line 4, please change "of grater than" to --of greater than--.

In column 72, line 4, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 72, line 6, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 72, line 65, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 73, line 1, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 73, line 62, please change "treatment is a" to --treatment includes a--.

In column 73, lines 63-65, please change "wherein said oxyperm polymerizable material is a fluorine macromer and said ionoperm polymerizable material" to --wherein said ionoperm polymerizable material--.

In column 74, line 16, please change "material comprises a fluorine macromer, and" to --material is formed from--.

In column 74, line 43, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 74, line 45, please change "0.4x10-6" to --$0.4x10^{-6}$--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Banner & Witcoff, Ltd.
10 South Wacker Drive
Suite 3000
Chicago, IL 60606

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In column 75, line 35, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 75, line 37, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 76, lines 3 and 4, please change "(b) polymerizing the core in an atmosphere substantially free from oxygen" to --(b) polymerizing the core formulation in an atmosphere substantially free from oxygen to form a biocompatible lens having a core and surfaces;--.

In column 76, line 8, please change "autoclaving lens" to --autoclaving said lens--.

In column 76, line 25, please change "wherein said ophthalmic lens" to --wherein said biocompatible lens--.

In column 77, lines 9 and 10, please change "54 including (c) said said lens being autoclaved at predetermined temperatures." to --54, said lens being sterilized.--

In column 77, line 39, please change "worn as extended wear lens that is worn for" to --worn as an extended wear lens for --.

In column 77, line 61, please change "continous" to --continuous--.

In column 78, line 9, please change "worn as extended wear lens that is worn for" to --worn as an extended wear lens for--.

In column 79, line 12, please change "6.4x10-6 " to --$6.4x10^{-6}$--.

In column 79, line 14, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 79, line 47, please change "continous" to --continuous--.

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ISSUE DATE: OCTOBER 4, 2005

INVENTORS: NICOLSON, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 80, line 18, please change "absorption" to --adsorption--.

In column 80, line 22, please change "0.4x10-6" to --$0.4x10^{-6}$--.

In column 80, line 24, please change "6.4x10-6" to --$6.4x10^{-6}$--.

In column 80, line 28, please change "continous" to --continuous--.

In Column 80, line 49, please change "less that about" to --less than about--.

In column 80, after line 49, please add the following claims:

85. An extended wear contact lens comprising a core polymeric material and inner and outer surfaces that are more hydrophilic than said core polymeric material, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said extended wear contact lens can be continuously worn for at least fourteen days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

86. A siloxane hydrogel contact lens comprising a core polymeric material having hydrophilically modified surfaces that are more hydrophilic that said core material, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

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PATENT NO. 6,951,894

APPLICATION NO. 09/640,526

ISSUE DATE: OCTOBER 4, 2005

INVENTORS: NICOLSON, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about 6.4×10^{-6} mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} cm^2/min to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said hydrogel contact lens is adapted for at least 14 days of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

87. A biocompatible contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface treated to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous contact for 14 days.

88. A biocompatible sterilizable contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to form surfaces that are more hydrophilic than said core material;

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ISSUE DATE: OCTOBER 4, 2005

INVENTORS: NICOLSON, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous contact for 30 days.

89. A contact lens comprising a polymeric material formed from at least:

(a) an ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide; and

(b) an oxyperm polymerizable material;

wherein said lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton ion permeability coefficient of greater than about 0.25×10^{-3} cm^2/sec, or (2) an Ionoflux diffusion coefficient of greater than about 1.3×10^{-5} mm^2/min, wherein said ion permeability is measured with respect to sodium ions;

wherein said lens is suitable for continuous, intimate contact with ocular tissue and ocular fluids while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours.

90. The contact lens of claim 89 wherein said ionoperm polymerizable material comprises both 2-hydroxyethyl methacrylate and N,N-dimethylacrylamide.

91. The contact lens of claim 90 wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer.

92. The contact lens of claim 91 wherein said polymeric material is further formed from ethylene glycol dimethacrylate.

93. The contact lens of claim 92 wherein said lens is autoclaved without lowering either said oxygen transmissibility or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

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PATENT NO. 6,951,894

APPLICATION NO. 09/640,526

ISSUE DATE: OCTOBER 4, 2005

INVENTORS: NICOLSON, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

94. The contact lens of claim 92 wherein said period of wear is at least 4 days.

95. The contact lens of claim 92 wherein said period of wear is at least 7 days.

96. The contact lens of claim 89 further comprising polyvinylpyrrolidone at a surface of said lens.

97. The contact lens of claim 96 wherein said polyvinylpyrrolidone coats said surface of said lens.

98. The contact lens of claim 89 wherein said period of wear is at least 4 days.

99. The contact lens of claim 89 wherein said period of wear is at least 7 days.

100. The contact lens of claim 89 wherein said lens has an equilibrium water content of about 10 to about 30 weight percent.

PATENT

Docket No.: 22841.018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Customer No.: 29277
NICOLSON et al.	:	Confirmation No.: 6172
Serial No.: 09/640,526	:	Group Art Unit: 1714
Filed: August 17, 2000	:	Examiner: Edward Cain
For: EXTENDED WEAR OPHTHALMIC LENS	:	

AMENDMENT AND RESPONSE UNDER 37 CFR §1.111 TO
OFFICE ACTION OF NOVEMBER 6, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on November 6, 2004, Applicants submit the following amendments and remarks, and a petition of a three month extension of the time to respond. The Examiner is requested to enter the following amendments and consider the accompanying remarks. Reconsideration is respectfully requested.

Amendments to the claims are reflected in the listing to the claims that begins on page 3 of this paper.

Support for the New Claims begin on page 28

Remarks begin on page 29 of this paper.

Enclosed with this paper is a Supplemental Information Disclosure Statement.

Also enclosed with this paper is a petition under 37 CFR § 1.136 for a three month extension of the time to respond, together with a Fee Transmittal form in duplicate authorizing the Commissioner to charge the petition fee under 37 CFR § 1.17(a)(3) for the extension and any other fees that may be due to Deposit Account Number 500417, McDermott Will & Emery, Washington D.C.

Please amend the claims as set forth below and enter the following remarks.

AMENDMENT TO THE CLAIMS:

Claims 1-158 (Cancelled).

Claim 159 (Currently Amended) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and flourine-containing monomers and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing [[-]]said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 77 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more biocompatible with the ocular tissue and ocular fluids than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens; [[,]]

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

Claim 160 (Previously Presented) The method of claim 159 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

Claim 161 (Previously Presented) The method of claim 159 wherein the surface modification treatment is a plasma treating process.

Claim 162 (Previously Presented) The method of claim 161wherein said oxyperm polymerizable material is a fluorine-containing macromer and said ionoperm polymerizable material is N-vinyl pyrrolidone.

Claim 163 (Currently Amended) An extended wear contact lens comprising a core polymeric material having ~~and~~ upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones; said core polymeric material having an oxygen permeability equal to or greater than 77 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and

irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

Claim 164 (Previously Presented) The extended contact lens of claim 163 wherein said core polymeric material comprises a fluorine containing macromer, and N-vinyl pyrrolidone.

Claim 165 (Previously Presented). The extended contact lens of claim 164 wherein said surfaces are modified by a plasma treating process.

Claim 166 (Previously Presented) The extended contact lens of claim 165 wherein said extended lens can be continuously worn for about 7 days with less than about 8% corneal swelling.

Claim 167 (Previously Presented) The extended contact lens of claim 163 wherein said extended lens is worn for about 30 days.

Claim 168 (Currently Amended) A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 77 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material having formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said lens has an oxygen permeability of at least about 77 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater ~~grater~~ than about 6.4 x 10^{-6} [10-6] mm^2 [mm2]/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} [10-6] cm^3 [cm2]/min, wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes, wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

Claim 169 (Previously Presented) The hydrogel contact lens of claim 168 wherein said core polymeric material comprises a fluorine containing macromer as said oxyperm material and N-vinyl pyrrolidone as said ionoperm material.

Claim 170 (Previously Presented) The hydrogel contact lens of claim 169 wherein said surfaces are modified by a plasma treating process.

Claim 171 (Previously Presented) The hydrogel contact lens of claim 170 wherein said lens can be worn for about 7 days with less than about 8% corneal swelling.

Claim 172 (Previously Presented) The hydrogel contact lens of claim 170 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

Claim 173 (Previously Presented) The hydrogel contact lens of claim 170 wherein said lens can be continuously worn for about 30 days.

Claim 174 (Previously Presented) The hydrogel contact lens of claim 169 wherein said lens has an oxygen permeability of at least about 81 barrers.

Claim 175 (Currently Amended) A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to

extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has an oxygen permeability equal to or greater than 77 barrers, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes: wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids; wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids; and wherein said ophthalmic lens has an oxygen permeability of at least about 70 barters and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4 x $\underline{10^{-6}}$ [10-6] $\underline{cm^2}$ [cm2] /sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4 x $\underline{10^{-6}}$ [10-6] mm2 /min, wherein said ion permeability is measured with respect to sodium ions; said method comprising the steps of:

(a) applying said lens to the ocular environment, and

(b) allowing said lens to remain in intimate contact with the ocular environment for a period of at least 24 hours.

Claim 176 (Previously Presented) The method of claim 175 wherein said lens has an oxygen permeability of at least about 81 barrers.

Claim 177 (Previously Presented) The method of claim 175 wherein said intimate contact period is at least 4 days.

Claim 178 (Previously Presented) The method of claim 175 wherein said intimate contact period is about 7 days.

Claim 179 (Previously Presented) The method of claim 175 wherein said intimate contact period is about 14 days.

Claim 180 (Previously Presented) The method of claim 175 wherein said intimate contact period is about 30 days.

Claim 181 (Previously Presented) The method of claim 175, wherein said lens produces, after wear of about 24 hours, including normal steep periods, less than about 8% corneal swelling.

Claim 182 (Previously Presented) The method of claim 175, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 6% corneal swelling.

Claim 183 (Previously Presented) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

Claim 184 (Previously Presented) The method of claim 183 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

Claim 185 (Currently Amended) The method of claim 183 wherein the surface modification treatment includes [is] a plasma treating process.

Claim 186 (Currently Amended) The method of claim 185 wherein [said oxyperm polymerizable material is a fluorine macromer and] said ionoperm polymerizable material is N-vinyl pyrrolidone.

Claim 187 (Previously Presented) An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treament process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

Claim 188 (Currently Amended) The extended contact lens of claim 187 wherein said core polymeric material is formed from N-vinyl pyrrolidone.

Claim 189 (Previously Presented) The extended contact lens of claim 188 wherein said surfaces are modified by a plasma treating process.

Claim 190 (Previously Presented) The extended contact lens of claim 189 wherein said extended lens can be continuously worn for about 7 days with less than about 7 % corneal swelling.

Claim 191 (Currently Amended) The extended contact lens of claim 187 wherein said extended ~~wended~~ wear lens can be worn for about 30 days.

Claim 192 (Currently Amended) A siloxane hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion

permeability, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater ~~grater~~ than about 6.4×10^{-6} ~~10-6~~ mm2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} ~~10-6~~ cm^2 [cm2] /min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

Claim 193 (Previously Presented) The hydrogel contact lens of claim 192 wherein said core polymeric material is formed from N-vinyl pyrrolidone as said ionoperm material.

Claim 194 (Previously Presented) The hydrogel contact lens of claim 193 wherein said surfaces are modified by a plasma treating process.

Claim 195 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens can be worn for about 7 days in continuous contact with ocular tissues and fluids with less than about 8% corneal swelling.

Claim 196 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

Claim 197 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens can be continuously worn for about 30 days.

Claim 198 (Previously Presented) The hydrogel contact lens of claim 194 wherein said lens has an oxygen permeability of at least about 77 barrers.

Claim 199 (Currently Amended) A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has an oxygen permeability equal to or greater than 69 barrers, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes;

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids;

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids without having substantial amounts of lipid absorption; and

wherein said ophthalmic lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4 x $\underline{10^{-6}}$ [10-6] $\underline{cm^2}$ [cm2]/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4 x $\underline{10^{-6}}$ [10-6] $\underline{mm^2}$ [mm2]/min, wherein said ion permeability is measured with respect to sodium ions;

said method comprising the steps of:

(a) applying said lens to the ocular environment, and

(b) allowing said lens to remain in continous intimate contact with the ocular environment for a period of at least 24 hours without having substantial amounts of lipid adsorption.

Claim 200 (Previously Presented) The method of claim 199 wherein said lens has an oxygen permeability of at least about 77 barrers.

Claim 201 (Previously Presented) The method of claim 199 wherein said intimate contact period is at least 4 days.

Claim 202 (Previously Presented) The method of claim 199 wherein said intimate contact period is about 7 days.

Claim 203 (Previously Presented) The method of claim 199 wherein said intimate contact period is about 14 days.

Claim 204 (Previously Presented) The method of claim 199 wherein said intimate contact period is about 30 days.

Claim 205 (Previously Presented) The method of claim 199, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

Claim 206 (Previously Presented) The method of claim 199, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less than about 6% corneal swelling.

Claim 207 (Currently Amended) A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

(a) forming a pre-polymer core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said reactive components formulation;

(b) polymerizing the core formulation in an atmosphere substantially free from oxygen to form a biocompatible lens having a core and surfaces;

(c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and

(d) autoclaving said lens at predetermined temperatures;

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said biocompatible ~~ophthalmic~~ lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} [10-6] cm^2 [cm2] /sec or (2) by an Ionoflux Ion Permeability Coefficient of greater than about 1.5×10^{-6} [10-6] mm^2 [mm2]/min, wherein said ion permeability is measured with respect to sodium ions.

Claim 208 (Previously Presented) A method of forming a contact lens having high oxygen permeability and high water permeability, said method comprising:

(a) forming a polymeric core material in the shape of a contact lens having an inner and outer surface; and

(b) altering the surfaces of said core material to produce new surfaces that are more hydrophilic than said core material,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours.

Claim 209 (Previously Presented) The method of claim 208 wherein said intimate contact period is about 7 days.

Claim 210 (Previously Presented) The method of claim 208 wherein said intimate contact period is about 30 days.

Claim 211 (Previously Presented) The method of claim 208 wherein said lens is autoclaved at predetermined temperatures.

Claim 212 (Previously Presented) A biocompatible contact lens having high oxygen permeability and high water permeability, said lens comprising:

(a) a polymeric core material in the shape of a contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to produce new surfaces that are more hydrophilic than said core material,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours.

Claim 213 (Previously Presented) The lens of claim 212 wherein said intimate contact period is at least 4 days.

Claim 214 (Previously Presented) The lens of claim 213 wherein said intimate contact period is about 7 days.

Claim 215 (Previously Presented) The lens of claim 213 wherein said intimate contact period is about 14 days.

Claim 216 (Previously Presented) The lens of claim 213 wherein said intimate contact period is about 30 days.

Claim 217 (Previously Presented) The lens of claim 212, said lens being sterilized. temperatures.

Claim 218 (Currently Amended) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as an extended wear lens [that is worn] for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

Claim 219 (Currently Amended) A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers, siloxane-containing mononers and fluorine-containing monomers, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having at least one continous pathway from said inner surface to said outer surface for oxygen transmission therethrough;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as an extended wear lens [that is worn] for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

Claim 220 (Previously Presented) The method of claim 219 wherein the surface modification treatment is selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes.

Claim 221 (Previously Presented) The method of claim 219 wherein the surface modification treatment is a plasma treating process.

Claim 222 (Previously Presented) The method of claim 221 wherein said oxyperm polymerizable material is a siloxane containing macromer or siloxane containing monomer and said ionoperm polymerizable material is N-vinyl pyrrolidone.

Claim 223 (Previously Presented) An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers, siloxane containing monomers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least

one continuous pathway from said upper surface to said lower surface for oxygen transmission; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

Claim 224 (Previously Presented) The extended contact lens of claim 223 wherein said core polymeric material is formed from a mixture comprising a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone.

Claim 225 (Previously Presented) The extended contact lens of claim 224 wherein said surfaces are modified by a plasma treating process.

Claim 226 (Previously Presented) The extended contact lens of claim 225 wherein said extended lens can be continuously worn for about 7 days with less than about 8 % corneal swelling.

Claim 227 (Previously Presented) The extended contact lens of claim 224 wherein said extended wear lens can be worn for about 30 days.

Claim 228 (Currently Amended) A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about $6.4 \times \underline{10^{-6}}$ [10-6] $\underline{mm^2}$ [mm2]/sec or an Ionoton Ion Permeability Coefficient of greater than about $0.4 \times \underline{10^{-6}}$ [10-6] $\underline{cm^2}$ [cm2] /min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

Claim 229 (Previously Presented) The hydrogel contact lens of claim 228 wherein said core polymeric material comprises a siloxane-containing macromer or a siloxane containing monomer as said oxyperm material and N-vinyl pyrrolidone as said ionoperm material.

Claim 230 (Previously Presented) .The hydrogel contact lens of claim 229 wherein said surfaces are modified by a plasma treating process.

Claim 231 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens can be worn for about 7 days with less than about 8% corneal swelling.

Claim 232 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens is worn for about 7 days with less than about 4% corneal swelling.

Claim 233 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens can be continuously worn for about 30 days.

Claim 234 (Previously Presented) The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 barrers .

Claim 235 (Currently Amended) A method of using a contact lens as an extended wear lens, said lens having ophthalmically compatible modified surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion or water permeability, and which has at least one continous pathway between said modified surfaces for oxygen surfaces, said polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said modified surfaces are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes;

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids;

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids without having substantial amounts of lipid absorption; and

wherein said ophthalmic lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10^{-6} [10-6] cm^2 [cm2] /sec or (2) an Ionoflux Diffusion Coefficient of greater than about 6.4 x 10^{-6} [10-6] mm^2 [mm2]/min, wherein said ion permeability is measured with respect to sodium ions:

said method comprising the steps of:

(a) applying said lens to the ocular environment, and

(b) allowing said lens to remain in continuous ~~continous~~ intimate contact with the ocular environment for a period of at least 24 hours.

Claim 236 (Previously Presented) The method of claim 235 wherein said lens has an oxygen permeability of at least about 77 barrers.

Claim 237 (Previously Presented) The method of claim 235 wherein said intimate contact period is at least 4 days.

Claim 238 (Previously Presented) The method of claim 235 wherein said intimate contact period is about 7 days.

Claim 239 (Previously Presented) The method of claim 235 wherein said intimate contact period is about 14 days.

Claim 240 (Previously Presented) The method of claim 235 wherein said intimate contact period is about 30 days.

Claim 241 (Previously Presented) The method of claim 235, wherein said lens produces, after wear of about 24 hours, including normal steep periods, less than about 8% corneal swelling.

Claim 242 (Previously Presented) The method of claim 235, wherein said lens produces, after wear of about 7 days, including normal sleep periods, less that about 6% corneal swelling.

Claim 243 (Currently Amended) An extended wear contact lens comprising a core polymeric material and inner and lower ~~lewer~~ surfaces that are more hydrophilic than said core polymeric material, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability, said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said extended wear contact lens can be continuously worn for at least fourteen days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

244 (Currently Amended) A siloxane hydrogel contact lens comprising a core polymeric material having hydrophilically modified surfaces that are more hydrophilic that said core material, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about 6.4 x 10^{-6} ~~10-6~~ mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x

10^{-6} ~~10-6~~ cm^2/min to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said hydrogel contact lens is adapted for at least 14 days of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

Claim 245 (Currently Amended) A biocompatible contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} ~~10-6~~ cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface treated ~~(modified)~~ to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous ~~continous~~ contact for 14 days.

Claim 246 (Currently Amended) A biocompatible sterilizable contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} ~~10-6~~ cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continuous ~~continous~~ contact for 30 days.

Claim 247 (New) A contact lens comprising a polymeric material formed from at least:

(a) an ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide; and

(b) an oxyperm polymerizable material;

wherein said lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton ion permeability coefficient of greater than about 0.25×10^{-3} cm^2/sec, or (2) an Ionoflux diffusion coefficient of greater than about 1.3×10^{-3} mm^2/min, wherein said ion permeability is measured with respect to sodium ions;

wherein said lens is suitable for continuous, intimate contact with ocular tissue and ocular fluids while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours.

Claim 248 (New) The contact lens of claim 247 wherein said ionoperm polymerizable material comprises both 2-hydroxyethyl methacrylate and N,N-dimethylacrylamide.

Claim 249 (New) The contact lens of claim 248 wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer.

Claim 250 (New) The contact lens of claim 249 wherein said polymeric material is further formed from ethylene glycol dimethacrylate.

Claim 251 (New) The contact lens of claim 250 wherein said lens is autoclaved without lowering either said oxygen transmissibility or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

Claim 252 (New) The contact lens of claim 250 wherein said period of wear is at least 4 days.

Claim 253 (New) The contact lens of claim 250 wherein said period of wear is at least 7 days.

Claim 254 (New) The contact lens of claim 247 further comprising polyvinylpyrrolidone at a surface of said lens.

Claim 255 (New) The contact lens of claim 254 wherein said polyvinylpyrrolidone coats said surface of said lens.

Claim 256 (New) The contact lens of claim 247 wherein said period of wear is at least 4 days.

Claim 257 (New) The contact lens of claim 247 wherein said period of wear is at least 7 days.

Claim 258 (New) The contact lens of claim 247 wherein said lens has an equilibrium water content of about 10 to about 30 weight percent.

SUPPORT FOR THE NEW CLAIMS

Claims 247 to 258 are new. Support for the new claims can be found throughout the detailed specification and original claims. For example, detailed support for claim 247 can be found on page 10, beginning at line 23, where applicants describe ionoperm polymerizable materials to include 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide; under Tables E on pages 91, applicants describe preferred Ionoton values of greater than about 0.25×10^{-3} cm^2/sec in Table F on pager 96 and in Example F 5 applicants further describe Ionoflux values including those greater than about 1.3×10^{-5} mm^2/min. Additional support for claim 249 can be found under the section labeled oxyperm polymerizable materials on page 9 of specification; support for claim 250 can be found on page 11, line 11; support for claims 254 and 255 can be found in Examples F 1 to F 12 and Table F on pages 91-96; support for claims 251 to 253 and 256 to 258 should be readily apparent from the disclosure. Accordingly, it is respectfully submitted that the addition of new claims 247 to 258 does not raise any new matter issues.

REMARKS:

In the Office Action mailed on November 6, 2004, the Examiner allowed claims 183-242 and rejected claims 243-246 under 35 U.S.C. § 102(b) over Nicolson et al U.S. Patent No. 5,649,811. ("Nicolson '811 Patent"). The courtesy of the Examiner in allowing claims 183-242, believed to be claims 159-242, is appreciated.

For avoidance of doubt, the examiner is requested to indicate that pending claims 159 to 182 are also in condition for allowance, as reflected in the examiner's Notice of Allowability of December 2, 2002. Applicants believe that the omission of claims 159 to 182 as allowable was inadvertent, and have interpreted the Office Action as allowing these claims.

Applicant respectfully requests reconsideration of the pending claims in view of the above amendments to the claims and the following remarks.

In particular Applicants have made minor amendments to the claims marked "currently amended", as reflected above, to clarify the fact that superscripts are present in appropriate claims, and correct typographical errors.

THE REJECTION OF CLAIMS 243-246 IS OVERCOME AS THE NICOLSON '811 PATENT IS NOT PRIOR ART UNDER 35 U.S.C. § 102(b)

The Nicolson '811 Patent, SN 08/682,452, does not qualify as prior art. The Nicolson '811 Patent is a parent application of the present application as indicated in the filing receipt. Clearly, priority of SN 08/682,452 was claimed upon the August 17, 2000 filing date of the present application and such priority was granted by the filing receipt where the SN 08/682,452

application, now the Nicolson '811 Patent, is specifically identified. Accordingly, withdrawal of the rejection under claims 243-246 under 35 U.S.C. § 102(b) is requested.

New claims 247 to 258 claim a species of the invention. In particular, independent claim 247 claims a lens having a specific ionoperm polymerizable material, with the lens having a extended period of wear of 24 hours without substantial lipid adsorption. Dependant claims 248 to 258 depend on independent claim 247.

A notice of allowance is solicited.

For avoidance of doubt, applicants' additionally petition for an extension of time under 37 C.F.R. §1.136, which is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account Number 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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Date:	September 22, 2004	**Time Sent:**	
To:	**Company:**	**Facsimile No:**	**Telephone No:**
Mr. Edward Cain	U.S. Patent and Trademark Office	~~571-273-1118~~ 703-872-9306	
From:	Kenneth L. Cage	*Direct Phone:*	202.756.8363
E-Mail:	kcage@mwe.com		
Sent By:		*Direct Phone:*	
Client/Matter/Tkpr:	22841-018	*Original to Follow by Mail:*	No
		Number of Pages, Including Cover:	43

Re: Copy of May 6, 2004 PTO filing

Message:

Dear Mr. Cain:

Please find a copy of all documents filed on May 6, 2004 and the PTO-stamped postcard reflecting receipt of same. Please let me know if you need any additional documents.

Main Facsimile: 202.756.8087 Facsimile Operator: 202.756.8090

U.S. practice conducted through McDermott Will & Emery LLP.
600 Thirteenth Street, N.W. Washington, D.C. 20005-3096 Telephone: 202.756.8000

Applicant: Paul NICOLSON, et al. Docket No. 22841-018

Title: EXTENDED WEAR OPHTHALMIC LENS Serial/Req./Patent No. 09/640,526

Date Sent: 9/8/2004 ☒ Hand Carried ☐ Fax ☐ Electronic ☐ Cert. of Mailing ☐ Express Mail No

☒ Transmittal Letter

New Patent App ☐ Utility ☐ Design ☐ Cont. ☐ CIP ☐ Div. ☐ PCT ☐ RCE ☐ Prov

☐ Other:

_____ pages of Specification

_____ pages of Claims

_____ pages of Abstract

_____ pages of Formal/Informal Drawings

☐ Small Entity ☐ Large Entity

☐ Declaration/Power of Attorney

☐ Recordation of Assignment/Security Agreement

☒ Information Disclosure Statement

8 pp. Form PTO 1449

57 copies of cited references

☐ Preliminary Amendment

☐ Response to Missing Parts Notice

☐ Resp. to Notice to Correct App. Papers

☐ Certified Copy of Priority Doc.

☐ Claim for Convention Priority

☒ Response/Amendment to Office Action of November 6, 2003

☒ Request for Three month Extension of Time

OIPE JC#35 MAY 06 2004 PATENT & TRADEMARK OFFICE

☐ Letter submitting ____ pages of drawings

☐ Req. for Approval of Drawing Amendments

☐ Req. for Oral Hearing

☐ Not. of Appeal ☐ Appeal Brief ☐ Reply Brief

☐ Rule 312 Amendment/Letter

☐ Req. for Acknowledgement of Cited Art

☐ Issue Fee

☐ Publication Fee

☐ Req. for Certificate of Correction

☐ Maintenance Fee for ____ years after grant

☐ Fee Address Indication Form

☐ Terminal Disclaimer

☐ Petition to Commissioner

☐ Status Inquiry

☐ Other

Check Nr $		☐ Charge Deposit Acct. 500417	$1432	Atty Init.	KLC	Tkpr. #	3324	Secy. or PL:	L DONNELLY

CRS Descrip.: Code (2): $302 Code (5): $550 Code (10): $180

THE PATENT AND TRADEMARK OFFICE DATE STAMPED HEREON IS ACKNOWLEDGEMENT THAT THE ITEMS, CHECKED ABOVE, WERE RECEIVED BY THE PTO ON THE DATE STAMPED.

Docket No.: 22841-018 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	Customer Number: 20277
NICOLSON et al.	Confirmation Number: 6172
Serial No.: 09/640,526	Group Art Unit: 1714
Filed: August 17, 2000	Examiner: Edward Cain
For: EXTENDED WEAR OPHTHALMIC LENS	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is an Amendment in the above-identified application.

- ☐ No additional fee is required.
- ☐ Applicant is entitled to small entity status under 37 CFR 1.27
- ☒ Also attached: Petition for Extension of Time (Three-Months); Information Disclosure Statement, PTO-Form 1449 (6 pp); Sixty-Six (67) References

The fee has been calculated as shown below.

	NO. OF CLAIMS	HIGHEST PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	96	84	12	$18.00 =	$216.00
Independent Claims	13	12	1	$86.00 =	$86.00
		Multiple claims newly presented			$0.00
		Fee for extension of time			$950.00
					$0.00
				Total of Above Calculations	$1252.00

☒ Please charge my Deposit Account No. 500417 in the amount of $1252.00. An additional copy of this transmittal sheet is submitted herewith.

☒ The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment, to Deposit Account No. 500417, including any filing fees under 37 CFR 1.16 for presentation of extra claims and any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,
MCDERMOTT, WILL & EMERY

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Registration No. 26,151

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Facsimile: (202) 756-8087
Date: May 6, 2004

Applicant File No. 22841.018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#24
04-24-03

In re Application of:

Paul NICOLSON, et al. **Group Art Unit: 1714**

Serial No: 09/640,526 **Examiner: Edward Cain**

Filed: August 17, 2000

For: EXTENDED WEAR OPHTHALMIC LENS

Assistant Commissioner of Patents
Washington, D.C. 20231

Amendment

Dear Sir:

Please amend the claims as set forth below and enter the following remarks.

IN THE CLAIMS:

Please add the following claims:

91

243. (New). An extended wear contact lens comprising a core polymeric material and inner and lower lower surfaces that are more hydrophilic than said core polymeric material, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69

barrers; wherein said extended wear contact lens can be continuously worn for at least fourteen days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

191 cont.

244. (New). A siloxane hydrogel contact lens comprising a core polymeric material having hydrophilically modified surfaces that are more hydrophilic that said core material, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about 6.4 x 10-6 mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids,

wherein said hydrogel contact lens is adapted for at least 14 days of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

245. (New) A biocompatible contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface treated (modified) to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without

having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continous contact for 14 days.

91 cont.

246. (New) A biocompatible sterilizable contact lens having an oxygen permeability of at least about 69 barrers and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min, said lens comprising:

(a) a polymeric core material in the shape of contact lens having an inner and outer surface; and

(b) said surfaces of said core material being surface modified to form surfaces that are more hydrophilic than said core material;

said lens having adequate movement on the eye without blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial lipid adsorption, and without causing substantial wearer discomfort for a period of continous contact for 30 days.

Remarks:

I. Request for Examination of New Claims 243-246 and A Notice of Allowance.

Applicants have presented new claims 243-246. These new claims are generally based upon presently allowed claims 187, 192 and 212 and are changed in scope from these allowed claims. Specifically, claim 243 is generally based on claim 187, claim 244 is generally based on claim 192 and claims 245 and 246 are generally based upon claim 212.

The new claims reflect that the structure of the lens comprisises a core polymeric material having lens surfaces that are more hydrophillic than the polymeric core material. The claimed hyudrophilic contact lens surface is not limited to a lens surface made by any specific type of surface treatment but is limited only by the recited claim elements of each claim. Also, new claims 243 and 244 recite a fourteen (14) day period of continous wear,

new claim 245 recites a fourteen(14) day period of continous contact, and new claim 246 recites a thirty (30) day period of continous contact.

To the extent an interview will clarify any isssues now before the Examiner, the Applicant will be pleased to confer with the Examiner.

Respectfully submitted,

McDERMOTT, WILL & EMERY

Dated: March 10, 2003

By _____
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(NE)

Docket No.: 22841-018 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
Paul C. Nicolson, et al.	:	
Serial No.: 09/640,526	:	Group Art Unit: 1714
Filed: August 17, 2000	:	Examiner: Paul R. Michl

For: EXTENDED WEAR OPTHALMIC LENS

SUPPLEMENTAL AMENDMENT

Commissioner for Patents
Washington, DC 20231

Sir:

The following Amendment is supplemental to Applicant's response to the Office Action mailed July 6, 2001. Since Applicant's response filed February 11, 2002 is considered responsive to the Office Action, no fee is considered due upon entry of this Supplemental Amendment. Accordingly, entry of this Supplemental Amendment is respectfully solicited.

IN THE CLAIMS

217. (Twice Amended) The lens of claim 212, said lens being sterilized.

REMARKS

This Supplemental Amendment is being filed to correct a minor editorial error in Claim 217.

Serial No.: 09/640,526

To the extent necessary, a conditional petition for an extension of time under 37 C.F.R. 1.136 is hereby made. To this extent, please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT, WILL & EMERY

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Date: February 26, 2002
Facsimile: (202) 756-8087

Serial No.: 09/640,526

AMENDED CLAIM W/ MARKINGS TO SHOW CHANGES MADE

217. (Twice Amended) The lens of claim 212, [©] said lens being sterilized.

Applicant File No. 22841.018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Paul NICOLSON, et al.

Group Art Unit: 1714

Serial No: 09/640,526

Examiner: Paul R. Michl

Filed: August 17, 2000

For: EXTENDED WEAR OPHTHALMIC LENS

Assistant Commissioner of Patents
Washington, D.C. 20231

Response To Office Action and Amendment

Dear Sir:

In further response to the Office Action of July 6, 2001, ("Office Action") please amend the specification and claims as set forth below and enter the following remarks. The courtesy of the Examiner in conducting an interview on January 22, 2002 with Dr. Paul Nicolson, one of the inventors, Rob Gorman, Esq, one of the Ciba Vision patent attorneys and the undersigned is acknowledged with appreciation. During the interview, the representatives of the Applicants presented differences between the presently claimed invention and the references relied upon by the Examiner in the 35 U.S.C. § 103 rejection. In particular, the Applicants described why the dislcosures in the references related to "surface treatement" do not provide sufficient motiviation to one of ordinary

skill in the art to add surface treatement to the any of primary references. These arguments were persented without any prejudice to the Applicants position that the primary references do not describe all of the claimed elements of invention except as to surface treatment. Based upon the interview, the following Supplemental Amendment is presented for the Examiner's consideration.

IN THE SPECIFICATION:

Please Amend the Specification as follows:

Please replace the paragraph beginning at Page 1, line 3 and ending at line 5 of the patent specification with the following replacement paragraph.

> This application is a continuation of Serial No. 09/262,542, filed on March 4, 1999, which is a continuation of Serial No. 09/108,714, filed July 1, 1998, which is a divisional of application Ser. No. 08/682,452, filed July 16, 1996, which is a divisional of application Ser. No. 08/569,816, filed December 8, 1995, which is a continuation-in-part of U.S. Application No. 08/301,166, filed on September 6, 1994. Priority is also claimed under 35 U.S.C. §119 for German Application No. 95810221.2 filed on April 4, 1995 and Swiss Application No. 1496/95 filed on May 19, 1995.

IN THE CLAIMS:

Please amend the following claims:

187. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material formed from a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm

polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

188. (Amended). The extended contact lens of claim 187 wherein said core polymeric material formed from N-vinyl pyrrolidone.

192. (Amended). A siloxane hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material being formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, and

(b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of grater than about 6.4 x 10-6 mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

193. (Amended). The hydrogel contact lens of claim 192 wherein said core polymeric material is formed from N-vinyl pyrrolidone as said ionoperm material.

205. (Amended). The method of claim 199, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

207. (Amended). A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

(a) forming a pre-polymer core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said reactive components formulation;

(b) polymerizing the core in an atmosphere substantially free from oxygen;

(c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and

(d) sterilizing the lens;

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without

having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm^2 /sec or (2) by an Ionoflux Ion Permeability Coefficient of greater than about 1.5×10^{-6} mm^2 /min, wherein said ion permeability is measured with respect to sodium ions.

217. (Amended). The lens of claim 212, including © said lens being sterilized.

218. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

219. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers, siloxane-containing mononers and fluorine-containing monomers, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having at least one continous pathway from said inner surface to said outer surface for oxygen transmission therethrough;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens;

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be

worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

223. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine- containing macromers, siloxane containing monomers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least one continous pathway from said upper surface to said lower surface for oxygen treatment; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

224. (Amended). The extended contact lens of claim 223 wherein said core polymeric material is formed from a mixture comprising a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone.

228. (Amended). A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material [having] formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

Wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about 6.4 x 10-6 mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

234. (Amended). The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 barrers.

Remarks:

I. One of Ordinary Skill In the Art Would Not be Motivated to Combine The Secondary References With The Primary References.

As dicussed at the interview, Applicants again traverse the Office Action for the following reasons, as it would not be obvious to one combine the above primary references with any of the secondary references. To the contrary, there is no motivation to one of skill in the art to combine the references. As stated in the preceding response, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there **is some teaching, suggestion, or motivation to do** so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See, In re Fine, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also MPEP 2143.01.

In this case, the prior art could not be modified so as to result in the combination defined by the claims at issue, as such prior art would not have made the modification obvious. In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986). Recognizing, after the fact, that such a modification would provide an improvement or advantage, without suggestion thereof by the prior art, rather than dictating a conclusion of obviousness, is an indication of improper application of hindsight considerations. Simplicity and hindsight are not proper criteria for resolving obviousness. See, In re Warner, 379 F.2d 1011, 154, USPQ 173 (CCPA 1967).

Turning first to the primary references, and assuming *arguendo* that other claim elements are dislcosed, Lai U.S. Patent No. 5,034,461 (" '461 Patent) 5,760,100, Lai U.S. Patent 5,158,717 (" ' 717 Patent) , U.S. Patent No. 5,219, 965 (" '965 Patent") and U.S. Patent No. 5,334,681 (" '965 Patent) to Mueller et al all fail to describe any any effective surface treatment. Turning now to the secondary references, each of the references lacks sufficient motivation to one of ordinary skill in the art to conduct the surface treatment, as presently claimed. U.S. Patent No. 4,214,014 (" ' 014 Patent) to Hofer et al. describes surface modification for contact lenses, which uses a setup that actually sputters the surface of the contact lens away, cleaning the surface and oxidizing it. U.S. Patent No. 4,687,816 (" '816 Patent) discloses a treatment of a specific type of soft lens with a very specific acid anhydride while the lens is swollen, which cannot be fairly be extended to other type of lens. U.S. Patent No. 4,980,208 (" ' 208") describes a methodology for use with hard lenses, not silicone hydorgel lenses. U. S. Patent No. 5,391,589 (" ' 589 Patent) discloses grafting surfaces onto lenses; and specifically hard lenses, which is inapplicable to the present invention.

Based upon the description of the above secondary references, each of the references is very specific to a specific material, and one or ordinary skill in the art would not be motivated to use such techniques for surface treatment of the present invention. Clearly, there is no motivation in the secondary references that it would be desirable for

one of ordinary skill in the art to improve any lens of the primary references by the surface treatment methods of Hofer, Lin, Sugiyama, or Kiguchi.

II. For Clarity and in Order to Claim the Full Scope of Applicants Invention, The Above Claims Have Been Amended

For clarity, a Applicant's have amended the above claims to correct minor typographical corrections, and for further clarity of expression of the scope of the invention. The specific changes are set forth in the Appendix attached to this supplemental response.

The Applicants have also changed claims 207 and 217 to reflect the sterilization of the lenses, which to one of skill in the art may be carried out by autoclaving or other sterilization techniques. See, e.g., Example B5 at pages 69-70 where autoclaving of lens is described, and Websters New World Dictionary, Third College Edition (1988) describes "autoclaving" as "to sterilize."

III. Request for Reconsideration and A Notice of Allowance.

For the above reasons, Applicants request reconsideration of the above rejections, and issuance of a Notice of Allowance. To the extent a further interview will clarify any issues now before the Examiner, the Applicant will be pleased to confer with the Examiner.

Respectfully submitted,

MCDERMOTT, WILL & EMERY

Dated: February 11, 2002

By _____
Kenneth L. Cage
Registration No. 26,151

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Telephone: (202) 756-8000

APPENDIX

MARK UP OF AMENDMENTS TO SPECIFICATION AND CLAIMS

IN THE SPECIFICATION:

Please replace the paragraph beginning at Page 1, line 3 and ending at line 5 of the patent specification with the following replacement paragraph.

This application is a continuation of Serial No. 09/262,542, filed on March 4, 1999, which is a continuation of Serial No. 09/108,714, filed July 1, 1998, which is a divisional of application Ser. No. 08/682,452, filed July 16, 1996, which is a divisional of application Ser. No. 08/569,816, filed December 8, 1995, which is a continuation-in-part of U.S. Application No. 08/301,166, filed on September 6, 1994. Priority is also claimed under 35 U.S.C. §119 for German Application No. 95810221.2 filed on April 4, 1995 and Swiss Application No. 1496/95 filed on May 19, 1995.

IN THE CLAIMS:

A mark up of the amendment of the above claims is presented below:

187. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material formed from [comprising] a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionoperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and

irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

188. (Amended). The extended contact lens of claim 187 wherein said core polymeric material formed from [comprises a fluorine macromer, and] N-vinyl pyrrolidone.

192. (Amended). A siloxane hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material being [having] formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material, [,] and

(b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of grater than about 6.4 x 10-6 mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

193. (Amended). The hydrogel contact lens of claim 192 wherein said core polymeric material is formed from [comprises a fluorine containing macromer as said oxyperm material and] N-vinyl pyrrolidone as said ionoperm material.

205. (Amended). The method of claim 199, wherein said lens produces, after wear of about 24 hours, including normal sleep [steep] periods, less than about 8% corneal swelling.

207. (Amended). A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

(a) forming a pre-polymer [polymeric] core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said reactive components [lens] formulation;

(b) polymerizing the core in an atmosphere substantially free from oxygen;

(c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and

(d) autoclaving lens at predetermined temperatures;

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without

having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm^2 /sec or (2) by an Ionoflux Ion Permeability Coefficient of greater than about 1.5×10^{-6} mm^2 /min, wherein said ion permeability is measured with respect to sodium ions.

217. (Amended). The lens of claim 212, including © said lens being sterilized [at predetermined temperatures].

218. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

219. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

a) preparing a lens formulation comprising an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers, siloxane-containing mononers and fluorine-containing monomers, and an ionoperm polymerizable material, wherein said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;

b) placing said lens formulation in a lens mold;

c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyperm polymerizable material and said ionoperm polymerizable material of said lens formulation form separate oxyperm and ionoperm phases; said lens core material having at least one continous pathway from said inner surface to said outer surface for oxygen transmission therethrough;

d) removing said lens core material from said lens mold;

e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

f) hydrating the treated lens core material to produce a hydrated extended wear contact lens[,];

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

223. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine- containing macromers, siloxane containing monomers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least one continous pathway from said upper surface to said lower surface for oxygen treatment; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

224. (Amended). The extended contact lens of claim 223 wherein said core polymeric material is formed from a mixture comprising [comprises] a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone.

228. (Amended). A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material [having] formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater [grater] than about 6.4 x 10-6 mm^2/sec or an Ionoton Ion Permeability Coefficient of greater than about 0.4 x 10-6 cm^2/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

234. (Amended). The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 barrers [days].

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Nicolson, et al., U.S. Patent No. 6,951,894 for "EXTENDED WEAR OPHTHALMIC LENS"

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Total Number of Pages in This Submission	

Patent Number	6,951,894
Issue Date	October 4, 2005
First Named Inventor	Nicolson, et al
Art Unit	1714
Examiner Name	Edward Cain
Attorney Docket Number	003707.00009

ENCLOSURES *(check all that apply)*

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